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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,052	06/21/2006	Yasuo Kunugiza	082368-007000US	8162

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

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08/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,052	KUNUGIZA ET AL.	
	Examiner	Art Unit	
	JOANNE HAMA	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,9,10,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,9,10,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant filed a response to the Non-Final Action of February 7, 2008 on May 2, 2008. Claims 2-5, 7, 8, 11, 12, 15-45 are cancelled.

Claims 1, 6, 9, 10, 13, 14 are under consideration.

Maintained Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 9, 10, 13 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,247,620 ('620) in view of Slate et al., US Patent 6,406,456 ('456), patented June 18, 2002, for reasons of record, February 7, 2008.

Applicant's arguments filed May 2, 2008 have been fully considered but they are not persuasive.

Applicant indicates that obviousness can be overcome by a showing that the invention provides unexpected or surprising results. Applicant indicates that the instant specification (Example 2) teaches that needleless injection of an expression construct comprising a nucleic acid sequence encoding luciferase is 100 times more effective than needle injection. Further, Example 3 of the specification teaches that injection of the an HGF expression construct, with or without PGIS gene, accelerated wound healing and enhance blood flow within four days of wound creation (Applicant's response, pages 4-5). In response, this is not persuasive. While Applicant indicates higher transgene expression levels in tissue injected with a needleless syringe than with a needle syringe (specification, Examples 2 and 3), "(m)ere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). As such, because needleless syringes were known in the art to be a way of administering nucleic acids, it would have been obvious for an artisan to combine the teaching of '620 with that of Slate et al. in order to arrive at a method of administering a nucleic acid encoding HGF via a needleless syringe, regardless of whether or not an artisan was aware that the expression level of expression constructs administered via a needleless syringe was higher than that of administration via a needle syringe.

Thus, the claims remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 9, 10, 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al., 2002, American Journal of Pathology, 161: 1761-1772 in view of Slate et al., US Patent 6,406,456 ('456), patented June 18, 2002, for reasons of record, February 7, 2008.

Applicant's arguments filed May 2, 2008 have been fully considered but they are not persuasive.

Applicant indicates that as noted above in the obviousness-type double patenting rejection, an obviousness rejection can be overcome by showing that the claimed invention provides unexpected or surprising results (Applicant's response, page 5). In response, as discussed above, this is not persuasive because identifying a latent property in the prior art does not render nonobvious an otherwise known invention. As such, because the art provides guidance to combine an expression vector comprising a nucleic acid sequence encoding HGF with a needleless syringe to a wound, the claims are unpatentable.

Thus, the claims remain rejected.

Claims 13, 14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al., 2002, American Journal of Pathology, 161: 1761-1772 in view of Slate et al., US Patent 6,406,456 ('456), patented June 18, 2002, in view of Yamamoto et al., 1996, European Journal of Pharmacology, 302, 53-60, in view of Gaine, 2000, JAMA, 284: 3160-3168, in view of Ullrich et al., 2001, Biochimica et Biophysica Acta, 1532: 1-14, for reasons of record, February 7, 2008.

Applicant's arguments filed May 2, 2008 have been fully considered but they are not persuasive.

Applicant indicates that the primary references provide no evidence that a needleless syringe is a surprisingly effective means to administer polynucleotides and none of the secondary references (Yamamoto et al., Gaine, or Ullrich et al.) address this deficiency. Indeed, none of the references provide any evidence that administration of a gene encoding PGIS around a wound site would have any effect on wound healing (Applicant's response, pages 5-6). In response, this is not persuasive. With regard to the surprising result of high gene expression following administration of an expression construct via a needleless syringe, identifying a latent property in the prior art does not render nonobvious an otherwise known invention. With regard to the art not providing guidance for administration of a gene encoding PGIS around a wound site having any effect on wound healing, the Examiner has indicated that analog an of prostacyclin, also known as PGI2, called SM-10802, has been shown to treat skin wounds in mice (Yamamoto et al.). In addition to other analogs of prostacyclin, Gaine teaches that prostacyclin synthase (PGIS) can be used in prostacyclin-based treatments. As such,

because the art teaches that PGIS can be used in prostacyclin-based treatments, it would have been obvious for an artisan to substitute SM-10802 with that of prostacycline synthase (PGIS) in order to achieve the predictable result of treating wound.

Thus, the claims remain rejected.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/
Art Unit 1632